Color-flow duplex ultrasound scan versus computed tomographic scan in the surveillance of endovascular aneurysm repair

Kathleen G. Raman, MD, MPH, Nita Missig-Carroll, RN BSN, Tracey Richardson, RVT, Satish C. Muluk, MD, and **Michel S. Makaroun, MD,** *Pittsburgh, Pa*

Objective: **The purpose of this study is to compare both computed tomographic scan (CT) and color flow duplex ultrasound scanning (CDU) as surveillance modalities for clinically significant endoleaks and to evaluate concordance in abdominal aortic aneurysm (AAA) diameter measurements in patients after endovascular aneurysm repair (EVAR) in a busy hospital vascular laboratory.**

Methods: **We conducted a retrospective review of all patients who underwent endovascular repair of abdominal aortic aneurysms between February 1996 and November 2002 and had same-day CT and CDU studies. Ninety-seven patients enrolled in phase II clinical studies of Ancure devices had long-term follow-up with both modalities. The other patients underwent simultaneous studies, usually only at the 1-month postoperative visit. Peripheral vascular studies were performed by two certified vascular technicians; all CT scans were reviewed by one vascular surgeon. CT was used as the standard against which the sensitivity, specificity, negative predictive value, and positive predictive value of CDU in endoleak detection was determined. Statistics were performed by using the paired *t* test; a *P* value <.05 was considered significant. Kappa statistic was used to assess the correlation between CDU and CT in identifying endoleaks. The correlation between CT and CDU in AAA size measurements as well as in serial size measurements was also determined.**

Results: **Four hundred ninety-five same-day CT and CDU examinations were reviewed in 281 patients. Patients had an average follow-up of 34.6 months (range, 1 to 72 months). Thirty-five leaks were identified among the patients studied (12.4% overall). In comparison with CT, diagnosis of endoleak with ultrasound scanning was associated with a sensitivity of 42.9%, specificity of 96.0%, positive predictive value of 53.9%, and negative predictive value of 93.9%. The correlation between the two modalities was modest (κ statistic 0.427). The minor axis transverse diameter as measured by ultrasound and CT scans (4.81 ± 1.1 cm on CT and 4.55 ± 1.1 cm on ultrasound) correlated closely (r = .93, P < .001.) Seventy percent of paired studies differed by ≤5 mm. Changes in aneurysm size throughout follow-up were −.29 ± .71 cm on CT scan −.34 ± .57 cm on duplex ultrasound scan. The correlation coefficient was .65 (P < .001). There was no significant difference in the change as measured by either modality on the paired *t* test.**

Conclusions: **Although CDU demonstrates a high degree of correlation with CT scan in determining aneurysm size change over time, it has a low sensitivity and positive predictive value in endoleak detection. In the hospital vascular laboratory at a large tertiary care center, CDU cannot effectively replace CT scan in surveillance after EVAR. (J Vasc Surg 2003;38: 645-51.)**

Endovascular aneurysm repair (EVAR) has gained popularity since it was first reported by Parodi[1] in 1991. Since then, it has proven to be a useful alternative to open aneurysm repair in selected patients.[2,3] Although EVAR offers immediate advantages over open aneurysm repair, it carries with it the need for lifelong surveillance to monitor aneurysm size and for potential complications, including endoleak, change in aneurysm size, graft migration, structural graft failure, and limb outflow impairment caused by limb stenosis or occlusion. Current modalities for EVAR surveillance include computed tomography (CT) scan, color-flow duplex ultrasound scanning (CDU), abdominal radiograph, magnetic resonance imaging (MRI), and angiography. The search continues for an optimal means of surveillance for complications of EVAR, and the use of each modality continues to evolve. Both CT and CDU can detect endoleaks as well as size changes over time. Although CT scan can, in addition, detect graft migration, ultrasound scanning may be better suited to detect limb flow abnormalities.

Recent reports have suggested that CDU is as effective as, and in certain situations superior to, CT in endoleak detection after EVAR. These enthusiastic reports, however, were not easy to duplicate in most other laboratories.[4] The purpose of this study was to compare both CT scan and CDU performed in the vascular laboratory at a large tertiary care center, as modalities of surveillance for endoleak detection and change in aneurysm size over time after EVAR.

METHODS

We evaluated 281 patients who had undergone endovascular repair of abdominal aortic aneurysm (AAA) with the Ancure (247) (Guidant, Menlo Park, Calif) or AneuRX

From the Division of Vascular Surgery, Department of Surgery, University of Pittsburgh Medical Center.

Competition of interest: none.

Presented at the Thirty-first Annual Meeting of the Society for Clinical Vascular Surgery, Miami, Fla, Mar 4-9, 2003.

Reprint requests: Michel S. Makaroun, MD, Division of Vascular Surgery, Department of Surgery, University of Pittsburgh Medical Center, A1011 PUH, 200 Lothrop Street, Pittsburgh, PA 15213 (e-mail: makarounms@msx.upmc.edu).

0741-5214/2003/$30.00 + 0
doi:10.1016/S0741-5214(03)00909-1

(34) (Medtronic, Santa Rosa, Calif) endograft at the University of Pittsburgh Medical Center from February 1996 to November 2002. Of these patients, 97 had been enrolled in a phase II Food and Drug Administration protocol. Follow-up of these patients included same-day ultrasound, CT, and abdominal radiograph in the first postoperative month, then at 6 months, 12 months, and yearly thereafter. Patients who underwent routine endovascular aneurysm repair with commercial endografts underwent same-day studies only 30 days postoperatively. The residual follow-up was with CT scans only at the same intervals as the protocol patients. CDU was substituted if the patient had a contrast allergy or elevated creatinine. This study protocol was reviewed and approved by the Institutional Review Board of the University of Pittsburgh.

Duplex ultrasound. All duplex scans were performed by a registered vascular technologist in a fully accredited hospital vascular laboratory. An Acuson 128 XP ultrasound machine (Mountain View, Calif) and 3- to 5-MHz transducers were used. Patient encounters were scheduled for 45 minutes, with 20 minutes devoted to actual scanning. A protocol standardized for the vascular laboratory was used for assessing the abdominal aorta, aortic bifurcation, and iliac vessels. This protocol consisted of obtaining longitudinal and transverse views of the proximal, mid, and distal aorta and iliac arteries. Peak systolic velocities were obtained in the graft and then compared with velocities in the iliac vessels to assess for the presence of limb flow anomalies including stenosis or occlusion. Color flow duplex scanning and Doppler interrogation of the sac was used to rule out the presence of perigraft flow. Endoleak detection was based on direct visualization and spectral confirmation of perigraft flow into an aneurysm sac. All CDUs were reviewed by a vascular surgeon. The ultrasound scanning technologist and the surgeon reviewing the tapes were both unaware of the results of CT scan during any portion of the ultrasound scan examination or review. A technically adequate study was defined as a study that allowed visualization of the aneurysm sac and flow within the graft. All patients were asked to fast before they reported for the scan.

CT scan. Helical CT was performed with a Lightspeed QXi multi-detector-row CT scanner (General Electric Medical Systems, Milwaukee, Wis).[5] Precontrast studies were obtained routinely. Contrast CT scans were performed after a Smart Prep series. One hundred twenty-five milliliters of nonionic iodinated contrast medium were injected at a speed of 4 mL/second. CT scans were obtained with a 2.5-mm slice thickness throughout the scan, which started 1 cm above the celiac axis and ended at the femoral bifurcation. All CT scans were reviewed by a single vascular surgeon (M.S.M). Size measurements were all performed by using an electronic caliper tool. No delayed imaging was performed for the detection of questionable endoleaks in the cohort included in this report. A technically satisfactory study included all required portions of the examination, as noted previously.

Statistics. CT and ultrasound scanning studies were compared for the determination of aneurysm size, diagnosis of endoleak, and graft patency. Using CT as the standard, the sensitivity, specificity, positive predictive value, and negative predictive value of CDU was determined in endoleak detection. The patients who were enrolled in phase II studies had longitudinal follow-up. Aneurysm diameter (minor axis) was compared on serial examinations to assess for growth or shrinkage. For each paired CT and CDU examination studied, the mean pair difference was calculated and the hypothesis that this value was not different from zero was tested with the paired *t* test. The limits of agreement, representing the range within which 95% of the differences would be expected to occur, were calculated as the mean difference $\pm$ 1.96 times the SD of the differences, according to the method of Bland and Altman.[6] AAA size change was determined by subtracting minor axis measurements by CT and CDU from the previous measurement, which was separated by either 6 or 12 months. Statistical analysis included calculation of the Pearson correlation coefficient and the paired *t* test. Results are expressed as mean $\pm$SD, and a *P* value less than .05 was considered significant. The κ statistic was used to determine how well CT and CDU correlated in endoleak detection.

RESULTS

The charts, CT scans, and peripheral vascular studies of 281 patients (246 males, 35 females) with a mean age of 73 $\pm$ 7 (range, 47 to 90 years) were reviewed. A total of 494 postoperative same-day CT scans and CDU scans were obtained (3.8 $\pm$ 1.4 per patient; range, 1 to 7) over a 1- to 72-month follow-up period (mean 34.6 $\pm$ 2 months). All CT scans and CDU were technically satisfactory for determination of aneurysm size and presence of endoleak.

Endoleak. Thirty-five leaks were identified (12.4% overall). Twelve type I leaks were identified (Fig 1); 3 patients were treated with a proximal cuff extender, 4 underwent iliac stent placement, 4 leaks resolved with expectant management, and 1 patient refused follow-up. Twenty-three type II endoleaks were identified (Fig 2); 15 patients underwent coil embolization of either an IMA or lumbar artery, and 8 leaks resolved with expectant management. A comparison of endoleak detection by means of same-day CT and CDU is presented in the Table. Both modalities were concordant in 448 (91%) of the observations. In 46 (9%) of the paired studies, the two modalities indicated opposite findings. CDU did not detect endoleaks clearly noted on CT in 28 cases (false negatives), and it suggested a positive finding in 18 studies not confirmed by the CT scan (false positives). One of these patients had an endoleak on CDU in the early postoperative examination that resolved by 6 months. He went on to develop a type 2 endoleak from a lumbar artery 4 years later, which was then detected by CT, but not by CDU. There were no other instances of CDU initially identifying an endoleak not corroborated by CT scan. Using CT as the gold standard, diagnosis of endoleak with CDU was associated with a sensitivity of 42.9%, specificity of 96.0%, positive predictive value of 53.9%, and negative predictive value of 93.9%. The

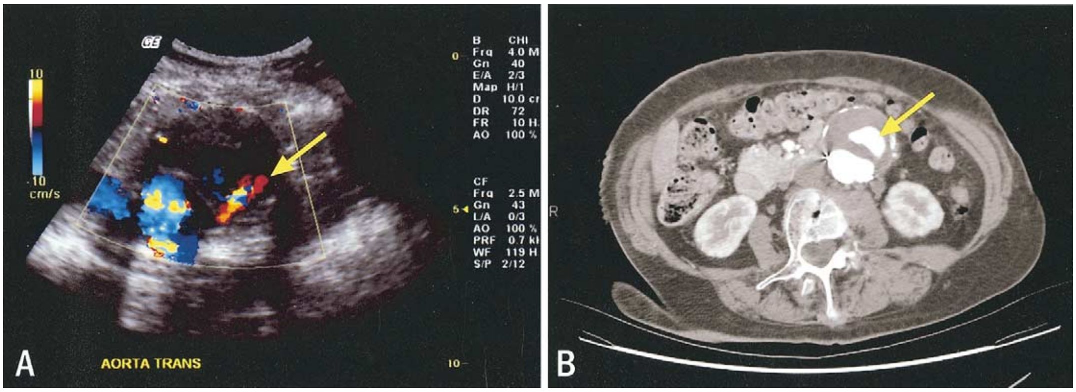

Fig 1. Example of proximal type I endoleak as depicted with **A**. Color duplex ultrasound scanning (*yellow arrow*). (**B**) CT scan (*yellow arrow*).

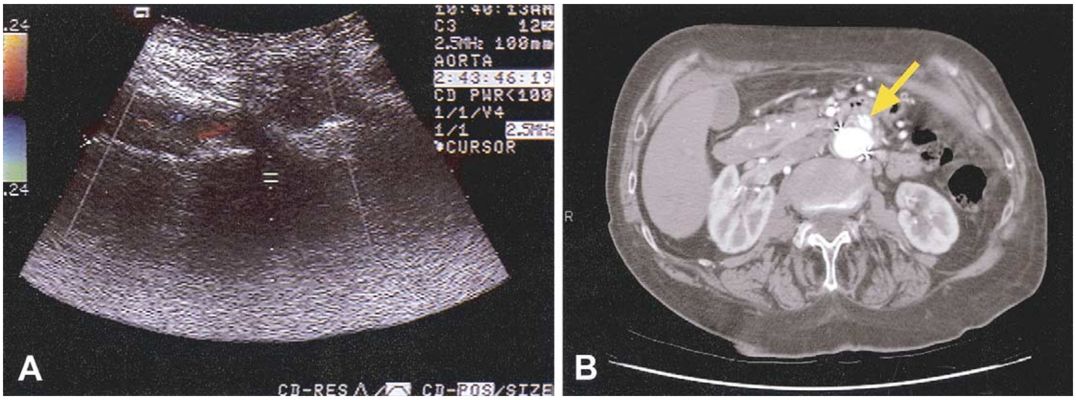

Fig 2. Example of type II endoleak originating from lumbar artery as depicted with **A**. Color duplex ultrasound scanning (*yellow arrow*). (**B**) CT scan (*yellow arrow*).

Correlation between CT and CDU for presence of endoleak postoperatively.

	CT scan	
CDU	*No endoleak*	*Endoleak*
No endoleak	427	28
Endoleak	18	21

measure of agreement between the two modalities was modest (κ statistic .427).

In order to determine the clinical significance of the false negatives on CDU, we further analyzed the outcomes of these patients. Eleven of the 28 false-negative examinations were identified as having type 1 endoleak by CT scan; seven of these patients required interventions, whether placement of proximal cuff extenders or iliac stents. Seventeen of the 28 false-negative examinations were identified as having type 2 endoleak by CT scan; eight of these patients required coil embolization of the sac as well as an IMA or lumbar artery. No patients with false-positive CDUs were noted to experience enlargements over time or require any intervention. One patient with an early endoleak noted only on CDU but not on CT actually developed a type II endoleak only detected on CT scan 4 years later, after all intervening tests were negative. The aneurysm of this patient is collapsed, and no intervention has yet been undertaken.

Aneurysm size. The minor axis diameter as measured by CT scan and CDU (4.81 ± 1.1 cm on CT and 4.55 ± 1.1 cm on CDU) correlated closely ($r = .93$, $P < .001$ [.89 to .97]) (Fig 3). However, there was a significant difference between the measurement of minor axis between CT and CDU by paired t test ($P < .001$). The Bland Altman plot (Fig 4) demonstrated consistent variability at all aneurysm diameters, with the CT measurement usually exceeding the CDU measurement. AAA size change was analyzed (using serial studies). Overall, 148 diameter measurements were calculated for each CT and CDU. Changes in aneurysm size were −.29 ± .71 cm on CT scan, −.34 ± .57 cm on CDU (Fig 5). The correlation coefficient was .65 ($P < .001$). There was no significant difference in the change in aneurysm diameter over time as measured by either modality on paired t test.

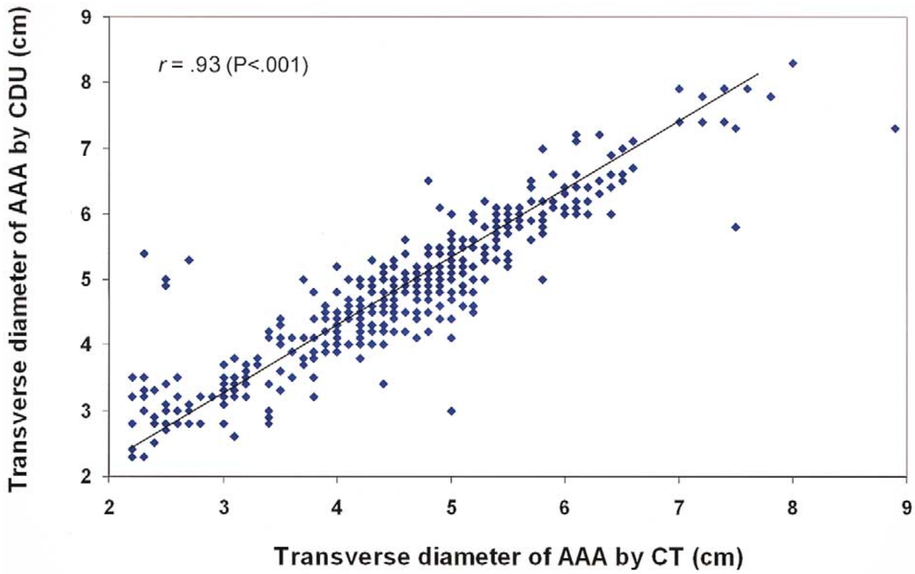

Fig 3. Correlation between postoperative CT and CDU (n = 494 pairs) for measurement of transverse aneurysm diameter (minor axis). Pearson correlation coefficient used to determine coefficient (r, +.93; $P < .001$). In 70% of the scans, diameter measurements differed by less than 5 mm.

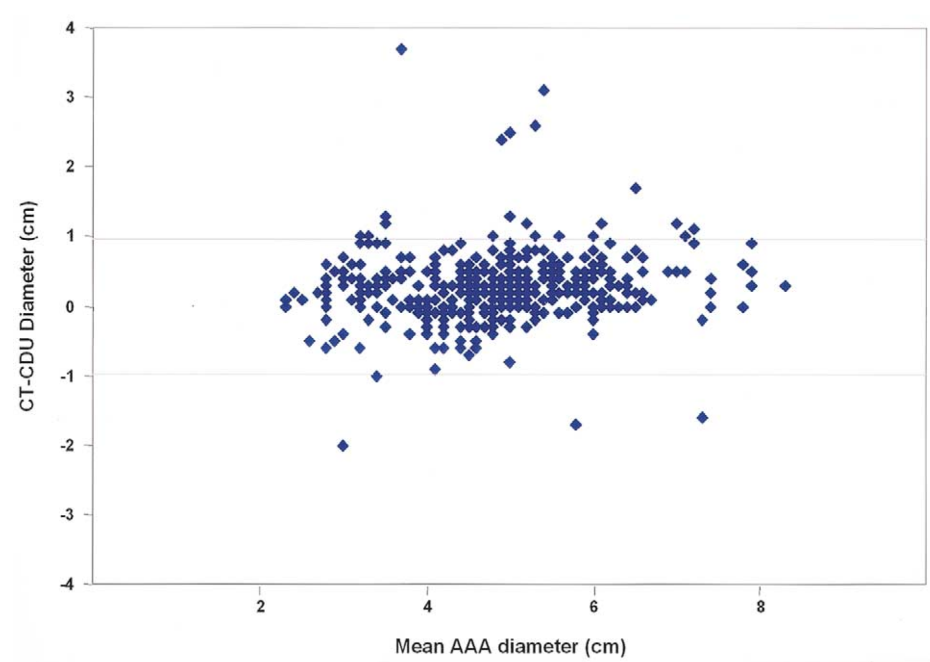

Fig 4. Bland Altman plot of postoperative CT and CDU measurement of aneurysm size. The mean difference between CT and CDU measurements plotted against mean aneurysm diameter. The limits of agreement (−.93 to .93) represent the range within which 95% of the differences would be expected to occur, and were calculated as the mean difference ± 1.96 times the SD of the differences.

DISCUSSION

After EVAR, the need for lifelong surveillance drives the search for an optimal means of monitoring aneurysm size changes, endoleak, structural failures, and limb abnormalities. A successful outcome may be defined as complete aneurysm exclusion without the presence of an endoleak. Although several series have placed the incidence of postoperative endoleak between 10% and 50%,[7-9] the clinical

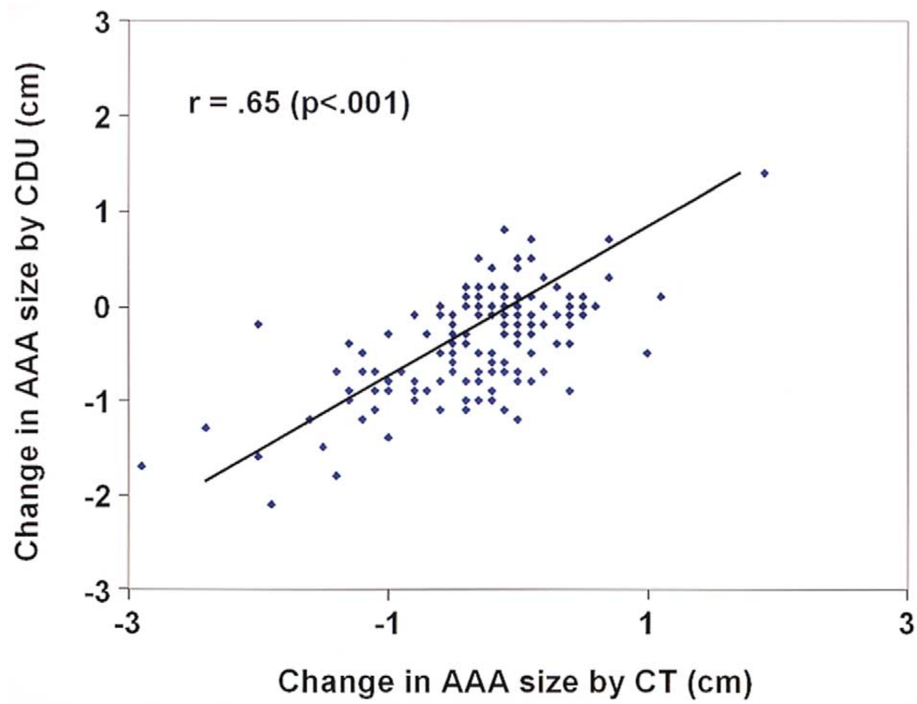

Fig 5. Comparison between CT and CDU for serial examinations of AAA size after EVAR (n = 148 pairs). Each point on plot represents the difference between two consecutive measures separated by 6 to 12 months. Pearson correlation coefficient used to determine coefficient (r, +.65; $P < .001$).

significance of these early endoleaks is not clear. Over 50% of initially identified endoleaks seal spontaneously, and the subsequent clinical course of patients with sealed endoleaks does not differ from patients who never had one documented.[10,11] Endoleak onset is highly variable and unpredictable. The problem is exemplified by a report of a patient with a sealed endoleak that later reopened, leading to nonfatal rupture.[10] A reliable and reproducible diagnostic tool is thus required for accurate follow-up of endoleaks in EVAR patients. The ideal tool would also be very accurate in detecting other parameters of failure or success. AAA size reduction over time has been used as a surrogate marker for successful exclusion, while enlargement has suggested either an endoleak or endotension.[12] Both CT and CDU can offer diagnostic help for endoleak detection and size reduction.

Although abdominal radiographs are useful to interrogate graft integrity and assess for evidence of device fatigue, CT scans have been used as the gold standard with which to assess aneurysm diameter and the presence of endoleaks.[13-16] The benefits of CT as an imaging modality over CDU include the fact that it is highly reproducible, less influenced by body habitus, and offers faster image acquisition. However, it is important to note that CT scans are not without their limitations, including repeated radiation exposure, potential contrast-related complications including allergy and worsening renal insufficiency, and high cost of serial examination. Further, Lederle[17] reported a significant degree of interobserver variability in AAA measurement (<2 mm in 65%, but may differ by >5 mm in 17%).

CDU is a potentially attractive alternative imaging technique. It is less invasive, less expensive, and does not require repeated exposure to radiation or to contrast agents. However, CDU is more operator-dependent and is significantly affected by the patients' body habitus and fasting status. In addition, ultrasound scanning measurements have been noted to underestimate the true size of the AAA when compared with CT, and they have at least as much inter-observer variability.[17]

Our results in this study show a size difference in AAA measurement by CT and CDU. These differences are small, and they are unlikely to be clinically significant in most cases, given that 70% of paired studies differed by ≤5 mm. There was a good correlation between CDU and CT in determining aneurysm size changes over time. This verifies that the detection of size change can be performed equally well by either modality. However, with a low sensitivity and positive predictive value, CDU at our site was not an effective means of endoleak detection. The correlation between CT and CDU was only modest. We obviously cannot exclude the possibility that endoleaks identified by CDU and interpreted as false positives are, in fact, true findings missed by the CT scan, especially in the absence of delayed CT imaging. To date, we have identified only one patient with a positive early CDU associated with a negative

CT who went on to develop an endoleak at 4 years that was then detected by CT scan only. Numerous technical factors influence the diagnostic value of a CT scan. Scan timing after the contract injection is crucial to detecting the arterial phase of the contrast and is helped by a Smart Prep series. However, endoleaks may fill slowly and cannot be identified on the early scan. Delayed images may be necessary when low-flow endoleaks are suspected. Our failure to use this technical refinement may have falsely elevated the detected CDU false positives, although we did not recognize late endoleaks on serial follow-up not detected by initial CT scans. Fine reconstructions on both the contrasted and noncontrasted images are essential to rule out artifacts, including plate-like calcifications in the AAA from being mistaken for endoleaks.

Similarly, technical factors can be very important in the diagnostic value of a CDU. Numerous recent reports from selected centers have documented excellent results using CDU in EVAR surveillance. Some even suggest a superiority of CDU over CT scan, claiming a higher sensitivity in detecting endoleaks proven by later clinical follow-up. Sato et al[4] reported excellent sensitivity (97%) and negative predictive value (98%) in the detection of endoleak. However, in reviewing 117 tapes of CDU examinations from 18 different centers, the same authors found only 19% of these studies to be technically adequate. Their findings suggest that serious differences exist between CDU studies performed at different locations due to technical issues limiting the general recommendation that CDU be the preferred method of follow-up. The factors involved in this variability are clear from these reports: Study time is quoted to average 90 minutes with high-end machines not uniformly available in many vascular laboratories. Technologist experience as well as deliberate extended scan times may be necessary to identify small or slow endoleaks. Modern scanners have significantly improved B mode imaging and Doppler functions that can identify not only the presence of endoleaks, but also the direction of flow in the endoleak.

Although our technologists are very experienced, our use of relatively older equipment and short scan times may have been the main culprit in the inadequate correlation between CDU and CT in the detection of endoleaks. Our Acuson 128 XP scanners were last upgraded in 1999, and although this study covered the period from 1996 to 2002, the equipment has since been supplanted by scanners with significant technical improvements. Nevertheless, we believe that most large hospital laboratories have not uniformly upgraded to newer equipment. Therefore, it is essential that clinical decisions based on CDU be undertaken only after a review of local results indicates equivalent or superior results with this modality when compared to CT scanning. Our review of a large number of same-day paired studies indicated that the excellent results reported recently by others could not be duplicated in a hospital vascular laboratory that can dedicate only 20 minutes of actual scan time to such an examination. Congested waiting lists for vascular studies and an inability to attract enough trained technologists have limited the ability of our hospital laboratory to devote longer time periods to each study. The lack of additional diagnostic utility of CDU over CT scanning under these conditions has led us to abandon CDU as a routine test for EVAR surveillance.

Heilberger et al[18] showed that the addition of a contrast agent (Levovist) during CDU examination greatly increased the sensitivity of CDU in endoleak detection. McWilliams et al[19] also showed that the addition of Levovist improved the sensitivity of CDU, but that there was an increased number of false positives; they attributed the overestimate of endoleak to either the blooming of color arising from adjacent vessels or to aneurysm wall inflammation. Most recently, Bendick et al[20] have reported on the use of a different ultrasound scanning contrast agent (Optison, Mallinckrodt, St Louis, Mo) combined with digitally encoded tissue harmonic imaging, which suppressed the artifacts associated with CDU and found no false positives. These adjuncts require modern equipment and can certainly improve the diagnostic utility of CDU if they can be applied effectively, thereby reducing the reliance on CT scanning. In addition to the equipment needed, the intravenous delivery of most of these agents and the typical hospital laboratory staffing with technologists who are neither skilled nor permitted to administer these agents have limited their widespread use. We had no access to this enhancing technology in our hospital's vascular laboratory.

Our results are not unique. Pages et al[21] reported a 42% sensitivity of CDU in endoleak detection but a fair reliability for surveillance of aneurysm diameter. Additionally, studies describing the use of adjunctive contrast agents in performing CDU have reported sensitivities of 12% for unenhanced ultrasound scanning and 50% for enhanced power Doppler,[19] concluding that even with the use of contrast agents, CT imaging remains the surveillance modality of choice.

Other measures obtained by various techniques may in time prove to increase the utility of these techniques in EVAR surveillance. Volume measurements obtained principally from 3-D reconstructions of CT data have been recently promoted as a more sensitive measure of successful exclusion and the absence or presence of endoleaks.[22] Such follow-up of volume data may offer early warning of inadequate exclusion of the AAA. On the other hand, Arko et al[23] recently reported that intrasac flow velocities may help in predicting whether type II endoleaks will seal spontaneously. Such technique refinements may in the future weigh in favor of adopting one technique over the other in routine follow-up.

The need for lifelong surveillance after EVAR mandates reliable diagnostic tools to detect potential complications. Our data suggest that the favorable results of CDU at selected centers cannot be reproduced everywhere. Caution should be exercised, and the individual reliability of CDU should be tested at the local facility before it is adopted as a suitable substitute for CT scanning. We conclude that ultrasound scanning performed in a hospital vascular laboratory such as ours cannot effectively replace a CT scan in surveillance after EVAR.

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Submitted Mar 18, 2003; accepted May 16, 2003.